INDIANA UNIVERSITY

SCHOOL OF MEDICINE

# Indiana University School of Medicine

# Industry Relations Policy

## Table of Contents


| | |
|---|---|
| Background | 2 |
| Introduction | 4 |
| Definitions | 5 |
| Enforcement | 6 |
| Disclosure of Conflict of Interest | 7 |
| Industry-Funded Speaking | 9 |
| Industry Support of Accredited Continuing Medical Education | 10 |
| Attendance at Industry-Sponsored Lectures and Meetings | 12 |
| Pharmaceutical Sales Representative Presence | 13 |
| Medical Device Representative Presence | 14 |
| Curriculum on Conflict of Interest and Extension of Policies to Community Educational Settings | 15 |
| Gifts and Meals | 17 |
| Consulting Relationships for Marketing | 19 |
| Consulting and Advising Relationships for Scientific Activities | 20 |
| Consulting or Participating with Financial Firms/Hedge Funds | 21 |
| Pharmaceutical Samples | 22 |
| Pharmacy and Therapeutics Committee | 24 |
| Ghostwriting and Honorary Authorship | 25 |
| Industry-Supported Fellowships | 26 |
| Proctoring | 27 |

## Background

Through this document, the Indiana University School of Medicine (IUSM) intends to provide an effective and practical set of rules and guidance for appropriately managing interactions between industry (as defined below) and IUSM faculty, trainees, medical students and staff, and in doing so, to reduce, manage or eliminate conflicts of interest. Establishing such rules and guidance entails being consistent and clear, as well as to provide an avenue of recourse for faculty, trainees, students and staff with questions or scenarios not specifically addressed in this document.

This policy was developed in conjunction with a thorough review of similar academic medical center policies as well as peer-reviewed literature and other important sources of information including the December 18, 2013, report of The Pew Charitable Trusts, titled, "Conflicts-of-Interest for Academic Medical Centers; Recommendations for Best Practices." The Institute of Medicine (IOM) report from 2014 entitled "Conflict of Interest and Medical Innovation; Ensuring Integrity While Facilitating Innovation in Medical Research" also outlined many important points that are carried forward below. However, such reports, the scholarly literature, regulatory rules and guidance, accreditation standards and other important resources underscore that evidence continues to be gathered and attitudes will evolve. Hence, IUSM will regularly revisit the rules contained in this document and in doing so will endeavor to keep pace with and address important developments as they arise. In this regard, IUSM faculty, trainees and staff are encouraged to bring new information to the attention of the IUSM Industry Relations Committee in order that it can be promptly evaluated and addressed as appropriate.

The goal of addressing conflicts of interest is to ensure that patient needs are met while simultaneously permitting faculty, trainees, students and staff to engage in appropriate interactions with industry that promote innovation. As such, this policy, like others at academic medical centers across the country, is a mechanism for reducing, eliminating or managing relationships with industry as opposed to reacting in a fashion that may impede important and appropriate collaborative efforts with industry. This IUSM policy is intended to enhance academic-industry relationships, support the objectivity of clinical and research activities, and maintain public trust. Because the subject-matter areas referred to in this document continue to evolve, it is not possible in a document like this to address every possible scenario or question. Hence, faculty, trainees and staff are encouraged to reach out to the committee for further guidance on matters not specifically addressed.

As written in the 2014 IOM report, several keys to principled industry collaboration exist, and are outlined in Box 1.

**Box 1 – Key to Principled Collaboration Between Academia and Industry**

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|---|---|
| 1. | Collaboration must always be first and foremost for the benefit of patients. |
| 2. | Researcher and health care autonomy and independence must be protected. |
| 3. | There must be reasonable access to meaningful and relevant information about how physicians, researchers, and companies engage in collaboration relationships. |
| 4. | All participants across the healthcare system must be accountable for their actions. |

**References:**


The Pew Charitable Trusts. Conflict-of-Interest policies for academic medical centers: recommendations for best practices. Washington DC. December, 2013. Report found at: http://www.pewtrusts.org/en/research-and-analysis/reports/0001/01/01/conflictsofinterest-policies-for-academic-medical-centers.

IOM (Institute of Medicine). 2014. Conflict of interest and medical innovation: ensuring integrity while facilitating innovation in medical research; Workshop summary. Washington, DC: The National Academies Press.

IOM (Institute of Medicine). 2009. Conflict of interest in medical research, education and practice. Washington, DC: The National Academies Press.

Institute on Medicine as a Profession – Conflict of Interest. Found at: http://imapny.org/conflicts-of-interest/conflicts-of-interest-overview/.

Korn D, Carlat D. Conflict of interest in medical education; recommendations from the Pew Task Force on medical conflicts of interest. *JAMA* 2013 310(22):2397-8.

## Introduction

The purpose of this policy is to establish Industry Relations COI guidelines around interactions with Industry representatives for faculty members of the Indiana University School of Medicine (IUSM). Interactions with Industry occur in a variety of contexts, including marketing of new pharmaceutical products, medical devices, and hospital and research equipment and supplies on-site, on-site training of newly purchased devices, the development of new devices, educational support of medical students and trainees, and continuing medical education. Faculty and/or trainees also might participate in interactions with Industry off campus and in scholarly publications in a variety of circumstances including consulting activities of various sorts. Some aspects of these interactions can have positive effects, and are important for promoting the educational, clinical and research missions of IUSM and for translating knowledge and expertise from the faculty to society and the community. However, these interactions must be ethical and cannot create Conflicts of Interest (COI) that could endanger patient safety, data integrity, the integrity of our education and training programs, or the reputation of either the faculty member or the institution. Individuals must consciously and actively separate clinical care decisions from any perceived or actual benefits expected from any company. It is not acceptable for patient care decisions to be influenced by the possibility of personal financial gain.

This policy is organized into domains, similar to those domains described in the Pew report outlined above. It is meant to address instances where a potential or perceived Industry Relations COI might arise, and provides explicit IUSM guidance on what is acceptable and what is not acceptable. It is impossible to anticipate every scenario or potential Industry Relations COI, but the policy addresses common areas found in academic medical centers such as IUSM.

**References:**

Kesselheim AS, Orentlicher D. Insights from a national conference: "Conflicts of interest in the practice of medicine." *J Law Med Ethics.* 2012;40(3):436-40.

Sah S. Conflicts of interest and your physician: psychological processes that cause unexpected changes in behavior. *J Law Med Ethics.* 2012;40(3):482-487.

Robertson C, Rose S, Kesselheim AS. Effects of financial relationships on the behaviors of health care professionals: a review of the evidence. *J Law Med Ethics.* 2012;40(3):452-466.

Lo B. The future of conflicts of interest: a call for professional standards. *J Law Med Ethics.* 2012;40(3):441-451.

Chimonas S, Evarts SD, Littlehale SK, Rothman DJ. Managing conflicts of interest in clinical care: the "race to the middle" at U.S. medical schools. *Acad Med.* 2013;88(10):1464-1470.

Campbell EG, Gruen RL, Mountford J, Miller LG, Cleary PD, Blumenthal D. A national survey of physician-industry relationships. *N Engl J Med* 2007;356:1742-50.

## Definitions

**Conflict of Interest**: a relationship which may place primary interests (e.g., public well-being or research integrity) at risk of being improperly influenced by the secondary, personal interests of the relationship.

**Personnel**: refers to all faculty, students, trainees and support personnel at IUSM.

**Faculty:** refers to all full-time and part-time IUSM faculty (i.e., those faculty with a primary appointment in the IUSM), irrespective of rank/classification.

**Trainee**: includes post-doctoral, graduate, and medical students, as well as residents and fellows.

**Industry** refers to any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, trust, enterprise, or other legal entity, whether for profit and not-for-profit, engaged in the manufacture, distribution or sale of diagnostic or therapeutic drugs, devices, supplies or services for clinical care, research or education. The term "Industry" does NOT include professional associations, not-for-profit volunteer health organizations, academic institutions or not-for-profit hospitals that are not substantially controlled by Industry and provide medical research/education-related products and services.

**Industry representative** or **Vendor:** includes any employee or agent of industry. An example of an "agent" is a commercial concern that organizes and sponsors educational activities or conducts surveys on behalf of Industry.

**Gifts:** refer to any material of worth, regardless of market value, received by Personnel from an Industry Representative or Vendor.

**Outside Professional Activities:** refers to the applicable IU policy that permits certain faculty members the opportunity to engage in outside activities, subject to various terms and conditions, including this Policy.

**Proctoring**: an assessment of skills based on observation by a credentialed individual with institutional privileges that may be used in lieu of data from a peer-review process or established criteria relating to minimal volumes of procedures performed. Proctoring, therefore, is a process administered through the hospital/clinic credentialing committee to objectively monitor, regulate or oversee individual privileging for its medical staff. By definition, proctoring is separate from precepting, in which an instructor or teacher (a preceptor) is responsible for the actions of a learning individual and is not, in whole or part, to promote an Industry.

**Proctor**: an independent and unbiased individual with procedural or intellectual skills in a position to evaluate and monitor the skills and ability of another individual. A proctor engages in proctoring.

**Speaker's Bureau**: a physician or a list of physicians who is/are engaged, recruited and/or trained by or on behalf of Industry to deliver information that is, in whole or in part, to promote Industry products to others in exchange for a fee or other considerations.

## Enforcement

The IUSM, through an Industry Relations Conflict of Interest Committee designated by the Dean, shall have the authority to administer this Policy. The designated committee will have the following responsibilities:

1. To advise personnel on the interpretation of this policy and to develop additional guidelines for its implementation, as necessary;

2. To refer instances of non-compliance with this policy, along with any recommended action, to the IUSM Dean or the Dean's designee and chair of the Industry Relations Conflict of Interest Committee, for final action. Any such action taken will be in accordance with applicable IUSM and university policies and procedures.

**References:**

Shnier A, Lexchin J, Mintzes B, Jutel A, Holloway K. Too few, too weak: conflict of interest policies at Canadian medical schools. *PLoS One* 2013;8(7):e68633.

Rothman DJ, Chimonas S. Academic medical centers' conflict of interest policies. *JAMA* 2010;304(20):2294-95.

## Disclosure of Conflict of Interest

Research:

Faculty and any personnel involved in the design, conduct or reporting of research are required to report to the university significant financial interests pursuant to National Institute of Health (NIH) regulations and University policies and procedures that were adopted to comply with NIH regulations.

Education of Trainees:

Regarding disclosure of potential Conflict of Interest in the educational setting of trainees and students, faculty must disclose, before commencing any lectures or presentations to students and trainees, any financial interests with Industry. The requirement to inform students and trainees should address the nature of the interest including the specific company and product and how they relate to the educational topic, whether in a lecture, seminar, rounds, team-based learning or other educational format.

Continuing Medical Education:

Specific to disclosure at continuing medical education events in which faculty participate as speakers or as organizers/planners of the events, faculty must abide by the Accreditation Council for Continuing Medical Education (ACCME) disclosure standards, to which the IUSM Division of CME adheres. ACCME focuses on relevant financial relationships with commercial interests in the 12-month period preceding the time that the individual is being asked to assume a role controlling content of the CME activity. ACCME considers relationships of the person involved in the CME activity to include relevant financial relationships of a spouse or partner.

Clinical:

When a financial interest relates to potential patient treatments, faculty should inform patients of such interests where appropriate and feasible.

Physician Payment Sunshine Act:

Faculty should also be aware of the Physician Payment Sunshine Act, which mandates that companies that participate in US federal health care programs disclose payments to physicians. These reports are available to the public on the Centers for Medicare and Medicaid (CMS) Open Payments website, found here: http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html.

All newly appointed IUSM faculty will be given a copy of this IUSM Industry Relations Policy and will be required to acknowledge receipt of the document. All current IUSM faculty will acknowledge understanding of this IUSM Industry Relations Policy on a yearly basis, similar to the IUSM Research-related Conflict of Interest policy.

**References:**

IOM (Institute of Medicine). 2012. Harmonizing reporting on potential conflicts of interest: a common disclosure process for health care and life science. Workshop Summary; Washington, DC: National Academies Press.

Reddi A. New guidelines for the disclosure of academic-industry financial ties and modeling professionalism during medical education. *JAMA Pediatr.* 2013;167(12):1091-1092.

Shaw DM. Beyond conflicts of interest: disclosing medical biases. *JAMA* 2014;312(7):697-698.

Lockhart AC, Bose MS, Kim ES, Johnson DH, Peppercorn JM, Michels DL, Storm CD, Schuchter LM, Rathmell WK. Physician and stakeholder perceptions of conflict of interest policies in oncology. *J Clin Oncol.* 2013;31(13):1677-1682.

Vera-Badillo FE, Ocana A, Templeton AJ, Tibau A, Amir E, Tannock IF. Raising concern about the American Society of Clinical Oncology conflict of interest policy amendment. *J Clin Oncol.* 2014;32:1.

Sharek Z, Schoen RE, Loewenstein G. Bias in the evaluation of conflict of interest policies. *J Law Med Ethics.* 2012;40(2):368-382.

Loewenstein G, Sah S, Cain DM. The unintended consequences of conflict of interest disclosure. *JAMA* 2012;307(7):669-70.

Miller ED. Creating an institutional conflict-of-interest policy at John Hopkins: progress and lessons learned. *Clev Clin J Med.* 2007;74 Suppl 2:S70-72.

## Industry-Funded Speaking

IUSM personnel are prohibited from presenting at programs designed solely or predominantly for company promotional, sales or marketing purposes even in those circumstances where the faculty retain control of the content of the presentation and/or any slides that may accompany the presentation; exception to this policy is when IUSM personnel are presenting at meetings for purposes related to developing Indiana University research discoveries for the market, as in the case of a faculty member speaking on behalf of her/his startup company. Examples of activities that are not appropriate for faculty participation include:

1. any arrangement or speaking engagement in activities commonly called a "Speakers Bureau";

2. inclusion on a list maintained by a commercial entity for the purpose of retaining or recommending an individual as a speaker, when the individual has agreed to be included on the list; and

3. participation as a speaker, panelist, presenter, or commentator in any activity or event funded, directly or indirectly, by a non-Indiana University intellectual property-related commercial entity, where the event is, or may be perceived to be, a promotional event for the sponsoring organization and/or its products or services.

Indirect funding includes financial support from a non-profit entity that is created and supported by commercial entity/entities. The limitations of this domain apply also to unpaid faculty when using their faculty title.

In certain limited circumstances when IUSM personnel have unique knowledge and expertise required for a particular event or occasion, it may be permissible for that faculty member to appear or present on behalf of industry. Such occasions include acting on behalf of industry as a consultant or advocate before a regulatory or other governmental agency (e. g., Food and Drug Administration) or before current or potential investors but only when the matter is related to the faculty member's own innovation or unique expertise such as speaking on behalf of the faculty member's startup company. Such appearances may be permitted, provided that advance approval for the activity is obtained from the Chair of the IUSM Industry Relations Conflict of Interest Committee.

**References:**


Avorn J. Rethinking the use of physicians as hired expert lecturers. *Ann Intern Med* 2014; 161(5): 363-364.

Berman HA, Boumil MM, Cutrell ES, Lowney KE. Pharmaceutical speakers' bureaus, academic freedom, and the management of promotional speaking at academic medical centers. *J Law Med Ethics* 2012; 40(2): 311-325.

Herder M, Reid L. The speakers' bureau system: a form of peer selling. *Open Med* 2013;7(2):e31-39.

## Industry Support of Accredited Continuing Medical Education

Continuing Medical Education (CME) activities take place in numerous locations, on the Indiana University School of Medicine (IUSM) campus as well as elsewhere throughout the city of Indianapolis, the state of Indiana, other states, and in virtual platforms. All CME activities, whether they originate from, are primarily organized by, or are merely hosted by the IUSM, must be accredited by the IUSM Division of Continuing Medical Education ("Division of CME") or authorized after consultation with the Division of CME, without regard to industry support. Irrespective of location, all Continuing Medical Education (CME) activities accredited or authorized by the Division of CME must comply with both the ACCME Standards for Commercial Support and this policy.

Industry is **prohibited** from exhibiting, displaying, or distributing promotional material on campus at IUSM activities. However, exhibits are permitted off-campus and industry funding in the form of unrestricted educational grants is permitted for any activity if the following conditions are met:

1. Industry support must be sought in collaboration with and under the auspices of the Division of CME and in accordance with ACCME rules.

2. The Division of CME shall manage the receipt and disbursement of all funds from industry, unless other arrangements are made with the prior consent and approval of the Division of CME.

**References:**

Steinman MA, Landefeld CS, Baron RB. Industry support of CME – are we at the tipping point? *N Engl J Med.* 2012;366(12):1069-1071.

Rothman SM, Brudney KF, Adair W, Rothman DJ. Medical communication companies and industry grants. *JAMA.* 2013;310(23):2554-2558.

Schwartz LM, Woloshin S. Medical communication companies and continuing medical education: clouding the sunshine? *JAMA.* 2013;310(23):2507-2508.

Rodwin MA. Drug advertising, continuing medical education, and physician prescribing: a historical review and reform proposal. *J Law Med Ethics.* 2010;38(4):807-815.

Kerridge I. Pharmaceutical industry support for continuing medical education: is it time to disengage? *J Paediatr Child Health.* 2011;47(10):690-692.

Spithoff S. Industry involvement in continuing medical education: time to say no. *Can Fam Physician.* 2014;60(8):694-696.

Dalsing MC. Industry working with physicians through professional medical associations. *J Vasc Surg.* 2011;54(3 suppl):41S-46S.

Brody, H. Pharmaceutical industry financial support for medical education: benefit, or undue influence. *J Law Med Ethics.* 2009;37(3):451-460.

## Attendance at Industry-Sponsored Lectures and Meetings

IUSM faculty, fellows, residents and medical students are discouraged from attending industry-sponsored events, dinners or other social events off campus unless these events meet the standards for accredited CME activities or for purposes related to developing Indiana University research discoveries for the market such as in the case of a faculty member speaking on behalf of her/his startup company. Faculty and fellows should be aware of the Physician Payment Sunshine Act (http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html), which mandates that meals from industry, which are commonly linked to industry-sponsored lectures, must now be reported and becomes part of the public domain. (Residents are excluded from Sunshine Act reporting, but fellows are not).

**Reference:**

Sismondo S. Key opinion and leaders and the corruption of medical knowledge: What the Sunshine Act will and won't cast light on. *J Law Med Ethics.* 2013;41(3):635-643.

## Pharmaceutical Sales Representative Presence

Pharmaceutical sales representatives should <u>not</u> be allowed access to IUSM faculty, staff or trainees. Faculty may appropriately choose to meet with <u>pharmaceutical industry scientists</u> for purposes such as discussing potential research collaborations or receiving in-depth educational information about the company's products and therapeutic areas. Such meetings may serve important research and educational functions and should be allowed as long as they are at the invitation of the faculty member and do not include sales representatives. For such meetings, pharmaceutical industry scientists should be permitted in the health center by appointment only and required to sign in at a designated office and wear an identification badge that clearly identifies them as vendors. Sales representatives are **<u>never</u>** permitted in patient care or designated medical education areas.

**References:**


Larkin I, Ang D, Avorn J, Kesselheim AS. Restrictions on pharmaceutical detailing reduced off-label prescribing of antidepressants and antipsychotics in children. *Health Aff (Milwood)* 2014;33(6):1014-1023.

Miller JE. From bad pharma to good pharma: Aligning market forces with good and trustworthy practices through accreditation, certification, and rating. *J Law Med Ethics.* 2013;41(3):301-610.

Alkhaled L, Kahale L, Nass H, Brax H, Fadlallah R, Badr K, Akl EA. Legislative, educational, policy and other interventions targeting physicians' interaction with pharmaceutical companies: a systematic review. *BMJ Open* 2014;4(7):e004880.

## Medical Device Representative Presence

Medical device representatives provide valuable technical assistance that cannot easily be obtained from other sources. There is a legitimate relationship between medical device industry representatives and members of the patient care teams that require flexibility around access to the academic medical center to ensure optimal patient care. This access of medical device representatives to patient care areas should be limited to <u>in-service training</u> and <u>technical assistance</u> on devices and other equipment already purchased, and then only by prior arrangement and with consent from the patients who would be involved.

For specific language on "Proctoring" related to implanting medical devices, please see the "Proctoring" domain.

**References:**


Donovan A, Kaplan AV. Navigating conflicts of interest for the medical device entrepreneur. *Prog Cardiovasc Dis.* 2012;55(3):316-320.

Hutchins JC, Rydell CM, Griggs RC, Sagsveen M, Bernat JL. American Academy of Neurology policy on pharmaceutical and device industry support. *Neurology* 2012;78(10):750-4.

LaViolette PA. Medical devices and conflict of interest: unique issues and an industry code to address them. *Clev Clin J Med.* 2007;74 Suppl 2: S26-S28.

## Curriculum on Conflicts of Interest and Extension of Policies to Community Educational Settings

Education in the diverse manifestations and settings of Industry Relations COI should be required for all trainees (medical students, residents, clinical fellows) and faculty. Understanding interactions between industry and health care practitioners should be a part of professional training, and it should be conveyed informally by role modeling and mentoring and formally via a defined curriculum. A formal curriculum on Industry Relations COI should aim to teach trainees and faculty how to think critically and appraise the evidence base for research reports, practice guidelines, and marketing materials to prevent marketing activities from inappropriately influencing their treatment decisions. Trainees should be educated on how to avoid or effectively manage Industry Relations COI and relationships with pharmaceutical and medical device industry representatives as they may be exposed to practice environments with more permissive standards of conduct regarding industry marketing.

Industry Relations COI policies written for medical schools and major teaching hospitals are generally understood to apply to faculty and trainees in those academic settings. Obliging community setting volunteer or adjunct faculty to abide by a stringent set of COI standards may alienate adjunct faculty, putting at risk a network that may be crucial for both patient referrals and outpatient medical training.

In community educational settings in which trainees or students might be exposed to industry marketing or representatives, the faculty should strive to provide and to model professional behavior. Trainees and students should be informed of the effect exposure to pharmaceutical and device representatives can have on their autonomy and objectivity. Trainees and students should be educated on how to think critically, appraise the evidence, avoid undue influence of industry, employ evidence-based medical practices, and commit to lifelong learning about scientific advances.

**References:**


Ross JS. Restricting interactions with industry to promote evidence-based prescribing. *JAMA Intern Med.* 2014;174(8):1290.

Austad KE, Avorn J, Campbell EG, Franklin JM, Kesselheim AS. Association of marketing interactions with medical trainees' knowledge about evidence-based prescribing: results from a national survey. *JAMA Intern Med.* 2014;174(8):1283-90.

Korenstein D, Roper N, Zhang N. Industry collaboration and randomized clinic trial design and outcomes. *JAMA Intern Med.* 2014:E1-E2.

Austad KE, Avorn J, Franklin JM, Kesselheim AS. Physician trainees' interactions with the pharmaceutical industry. *J Gen Intern Med.* 2013;28(10):1267.

Ramachandran R. Hams M. Silver-Isenstadt J. Physician trainees' interactions with the pharmaceutical industry. *J Gen Intern Med.* 2013;28(10):1266.

Austad KE, Avorn J, Kesselheim AS. Medical students' exposure to and attitudes about the pharmaceutical industry: a systematic review. *PLoS Med.* 2011;8(5):E1001037.

Epstein AJ, Busch SH, Busch AB, Asch DA, Barry CL. Does exposure to conflict of interest policies in psychiatry residency affect antidepressant prescribing? *Med Care.* 2013;51(2):199-203.

## Gifts and Meals

Industry representatives are prohibited from giving any item of value or gift to physicians and other faculty, staff, students and trainees at IUSM. IUSM faculty, staff, students and trainees may not accept any item of value or gift from industry representatives on the IUSM campus, including gifts of trivial material value. Moving an interaction with industry representatives to an off-campus location in order to avoid these restrictions would be in violation of this policy, and is itself prohibited. When attending off-campus meetings or conferences, faculty, staff, students and trainees are prohibited from accepting items of value or gifts from industry representatives.

Gifts containing industry brands and/or logos such as clocks, pens, post-it pads, posters, etc. are marketing tools, and should not be displayed in clinical and teaching areas. Anatomic models or charts that are deemed important for patient education are permitted, but non-branded versions are preferred.

While appropriate, mission-related relationships with Industry are important, it is neither necessary nor appropriate for Industry and Industry Representatives to provide IUSM personnel with meals. Therefore, the following rules shall apply:

1. Meals for IUSM-related events may not be directly funded by Industry, whether on campus or off campus.
2. Regarding meals for non-IUSM-related events, faculty that choose to accept meals during their Outside Professional Activities must be cognizant of the IU research-related Conflict of Interest policies and procedures and their responsibility to report the monetary value of meals funded by Industry, and that the value of such meals may be reportable under the Physician Payment Sunshine Act (http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html).

**References:**

King M, Essick C, Bearman P, Ross JS. Medical school gift restriction policies and physician prescribing of newly marketed psychotropic medications: difference-in-differences analysis. *BMJ.* 2013;346:f264.

Kesselheim AS. Drug company gifts to medical students: the hidden curriculum. *BMJ.* 2013;346:f1113.

Green MJ, Maters R, James B, Simmons B. Lehman E. Do gifts from the pharmaceutical industry affect trust in physicians? *Fam Med.* 2012;44(5):325-331.

Dana J, Loewenstein G. A social science perspective on gifts to physicians from industry. *JAMA*2009;290(2):252-255.

Davar M. Whose pen is being used to write your prescriptions? Normal gifts, conflicts of interest, and continuing medical education. *J Leg Med.* 2008;29(2):199-217.

Millard WB. Docking the tail that wags the dog: banning drug reps from academic medical facilities. *Ann Emerg Med* 2007;49(6):785-791.

## Consulting Relationships for Marketing

Consulting relationships with Industry that is solely or primarily for commercial marketing is prohibited. Exceptions may be provided for a faculty member engaged in activities related to his/her startup company. Any consulting relationship must clearly delineate and separate one's university responsibilities from consulting responsibilities and must not utilize or involve Indiana University resources, facilities, and/or people. Faculty are responsible for ensuring that their consulting activity and terms of any agreements meet the requirements of all Indiana University policies including but not limited to the Conflict of Commitment Policy (http://www.researchcompliance.iu.edu/Policies/coi/ConflictsCommitment.pdf), this Industry Relations Policy, and the Intellectual Property Policy (http://policies.iu.edu/policies/categories/administration-operations/intellectual-property/intellectual-property.shtml).

**References:**

Robertson C, Rose S, Kesselheim AS. Effect of financial relationships on the behaviors of health care professionals: a review of the evidence. *J Law Med Ethics.* 2012;40(3):452-466.

Samson RH. Private practice perspective on conflict of interest mandates. *J Vasc Surg* 2011;54(3 Suppl):15S-18S.

## Consulting and Advising Relationships for Scientific Activities

Faculty are encouraged and permitted to engage in consulting relationships with pharmaceutical and device companies about research and scientific matters, pursuant to and in compliance with applicable university policy. Faculty may provide valuable advice to pharmaceutical and device companies in the service of product innovation or refinement. Examples of such legitimate activities include:

1. Assistance in designing and overseeing clinical trials.

2. Technical assistance in creating or improving medical devices.

3. Advice on potential avenues for future scientific research.

Such consultation opportunities should be spelled out in written contracts with clear deliverables. Compensation must be of fair market value for comparable service. Such consulting relationships remain subject to the University's policies and procedures relating to Research Conflict of Interest, including reporting all applicable significant financial interests as per the following Indiana University-endorsed policy link: http://policies.iu.edu/policies/categories/academic-faculty-students/conditions-academic-employment/financial-conflicts-of-interest-in-research.shtml#policyStatement. More information about the research-specific Conflict of Interest disclosures and policies can be found here: http://www.researchcompliance.iu.edu/coi/index.html.

**References:**

Wright BD, Drivas K, Lei Z, Merril SA. Technology transfer: Industry-funded academic inventions boost innovation. *Nature* 2014; 507(7492):297-299.

Jain SH, Rosenblatt M, Duke J. Is big data the new frontier for academic-industry collaboration? *JAMA* 2014;311(21):E1-E2.

Anderson TS, Dave S, Good CB, Gellad WF. Academic medical center leadership on pharmaceutical company boards of directors. *JAMA* 2014;311(13):1353-1355.

Adkison CR, Cassell GH, Kahn JP, Meehan MJ, Pizzo PA, Stossel TP. Panel discussion: applications in the real world: Case studies in defining boundaries and managing innovation. *Clev Clin J Med.* 2007;74 Suppl 2:S51-S59.

Stossel TP. Regulating academic-industrial research relationships – solving problems or stifling process? *N Engl J Med.* 2005;353(10):1060-1065.

## Consulting or Participating with Financial Firms/Hedge Funds

Consulting with brokerage firms, hedge funds, financial advisors, or participating in groups that bring together physicians or scientists who provide expertise to business personnel on subject matter areas that relate to a faculty member's work or expertise within the university is prohibited.

**References:**


Pisano ED, Golden RN, Schweitzer L. Conflict of interest policies for academic health system leaders who work with outside corporations. *JAMA* 2014;311(11):1111-1112.

Pham-Kanter G. Revisiting financial conflicts of interest in FDA advisory committees. *Milbank Q* 2014;92(3):446-70.

Sah S, Fugh-Berman A. Physicians under the influence: social psychology and industry marketing strategies. *J Law Med Ethics*. 2013;41(3):665-72.

## Pharmaceutical Samples

Distribution of drug samples may influence prescribing patterns. However, such distribution may benefit disadvantaged patients and allow the prescribing physician to determine the individual tolerance and effectiveness of a given medication before committing the patient to more expensive full prescriptions.

Many of the clinical locations at which IUSM faculty, staff and trainees work have their own rules or standards addressing distribution of pharmaceutical samples. Faculty, students and staff are expected to honor the pharmaceutical samples rules and standards of the facility in which they are working.

Within the academic health system several sites have offered drug samples to patients. The following guidelines should be followed if pharmaceutical samples are provided to patients.

1. All drug samples must be deposited into a drug sample repository within the site where patient care is being delivered. There must be appropriate infrastructure and administrative processes in place before accepting samples into such a repository.

2. Drug samples may only be accepted by health system personnel who themselves are not the prescribers of the medications, and must be promptly directed to the designated secure repository where they are logged in.

3. All samples should be accepted by health system personnel not responsible for prescription of medications. Health care providers who will be prescribing medications in the repository should not accept drug samples.

4. Distribution of these samples must be in accord with the established procedures of the central repository. Ideally, after the request by a health care provider, retrieving medications from the repository should be performed by personnel not responsible for prescribing the medication. Accurate distribution records should be maintained. At a minimum this should include a record of patients receiving the sample, the prescribing health care provider, the drug name and lot number, and how many samples were distributed.

5. Free drug samples may <u>not</u> be used by Personnel for themselves, their families, or staff.

6. The decision by health care providers to distribute samples to patients must be based on sound medical rationale and not simply on the availability of samples in the repository.

7. The Pharmacy Department within a facility where a drug repository exists should conduct a yearly audit of the repository to determine if the presence of samples appears to be influencing prescribing practices among health care providers.

**References:**

Chren MM, Katz KA, Reid CC. Drug samples in dermatology: out of the closet, into the dustbin. *JAMA Dermatol* 2014; 150(5): 483-485.

Hurley MP, Lane AT, Stafford RS. Characterizing the relationship between free drug samples and prescription patterns for acne vulgaris and rosacea. *JAMA Dermatol* 2014;150(5): 487-493.

Howard DH. Drug companies' patient-assistance programs—helping patients or profits? *N Engl J Med.* 2014;371(2):97-99.

Tagore A. Drug promotion tactics-yet another pharma deception? *Int J Clin Pract.* 2014;68(6):662-665.

Barton D, Stossel T, Stell L. After 20 years, industry critics bury skeptics, despite empirical vacuum. *Int J Clin Pract.* 2014;68(6):666-673.

## Pharmacy and Therapeutics Committee

IUSM personnel with industry relationships may NOT serve as voting members of hospital and health system Pharmacy and Therapeutics committees. Voting members of Pharmacy and Therapeutics committees for hospitals and health systems affiliated with IUSM must comply with the policies and procedures of those committees on which they serve, and the hospital systems that govern those committees. Any IUSM personnel requesting changes or additions to the institution's formulary must also provide prior disclosure of financial relationships with pharmaceutical companies.

**References:**

Wen L. Patients can't trust doctors' advice if we hide our financial connections with drug companies. *BMJ.* 2014;348:g167.

Citrome L, Karagianis J, Maguire GA, Nierenberg AA. Pharmaism: a tale of two perspectives. *Int J Clin Pract.* 2014;68(6):659-661.

Nguyen NY, Bero L. Medicaid drug selection committees and inadequate management of conflicts of interest. *JAMA Intern Med* 2013;173(5):338-43.

## Ghostwriting and Honorary Authorship

Physicians and other healthcare professionals rely heavily on the information they read in journal articles and other sources of the medical literature to make diagnostic and therapeutic decisions, and they should be able to trust that any recommendations made reflect the research and opinions of the authors and not the hidden influence of writers hired by industry.

IUSM faculty, staff, students and trainees should follow the International Committee of Medical Journal Editors standards for authorship and contributorship (found here: http://www.icmje.org/), which require each author to contribute and participate meaningfully in the work.

IUSM faculty, staff, students and trainees are strictly prohibited from having publications or professional presentations of any kind, oral or written, ghostwritten by any party, industry or otherwise. This does not apply to transparent writing collaboration with attribution between academic and industry investigators, medical writers, and/or technical experts.

**References:**

Stretton S. Systematic review on the primary and secondary reporting of the prevalence of ghostwriting in the medical literature. *BMJ Open* 2014;4(7):e004777.

Bosch X, Hernandez C, Pericas JM, Doti P. Ghostwriting policies in high-impact biomedical journals: a cross-sectional study. *JAMA Intern Med* 2013;173(10):920-1.

Almassi B. Medical ghostwriting and informed consent. *Bioethics* 2013 Feb 28. doi: 10.1111/bioe.12017 [Epub ahead of print]

## Industry-Supported Fellowships

Industry has long played a role in funding scholarships, fellowships, and reimbursement of travel through travel grants. In order to make certain this valued relationship occurs in an appropriately supportive manner, IUSM has adopted the following guidelines:

1. All funds must be routed through an IU Foundation account in accordance with IUSM requirements.

2. Evaluation and selection of specific recipients of such funds must be the sole responsibility of IUSM with no involvement by the donor Industry. Thus, and by way of example, Industry may elect to support a fellowship in a specific area of advanced training, but Industry would not be invited or otherwise participate in the selection of individual recipients of the fellowship.

3. Disbursement of all such funds must be approved in advance by the IUSM Dean's Office or its designee.

4. The recipient of the funding is not subject to any conditions dictated by the funding entity.

**Reference:**

Singh N, Bush R, Dalsing M. Shortell CK. New paradigms for physician-industry relations: overview and application for SVS members. *J Vasc Surg* 2011;54(3 Suppl):26S-30S.

## Proctoring

Faculty may proctor other faculty within our institution as well as outside of hospitals and health systems unaffiliated with IUSM. All internal and external requests for proctoring should originate from a university or health system and NOT from industry. Payment to faculty for proctoring services performed outside of our health system should be at fair market value with clear deliverables outlined in writing.

**References:**


Heit M. Surgical proctoring for gynecologic surgery. *Obstet Gynecol* 2014; 123(2 Pt 1): 349-352.

Fargen KM, Frei D, Fiorella D, McDougall CG, Myers PM, Hirsch JA, Mocco J. The FDA approval process for medical devices: an inherently flawed system or a valuable pathway for innovation? *J Neurointerv Surg* 2013;5(4): 269-275.

Anderson MA, Banjeree S, Baron TH, Cash BD, Dominitz JA, Fanelli RD, Gan S, Harrison III ME, Ikenberry SO, Lee KK, Lichtenstein D, Shen B, Van Guilder T. Renewal of and proctoring for endoscopic privileges. *Gastrointest Endosc* 2008;67(1): 10-16.

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*Approved by IUSM Faculty Steering Committee on October 16, 2014*

*Approved by IUSM School Executive Committee on November 3, 2014*

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